

REMARKS

Reconsideration of the present application as amended is earnestly solicited. The original application includes 6 claims with claim 7 being added by preliminary amendment. Claims 2 and 6 have been amended to correct typographical errors in the claims.

No prior art rejection was issued with respect to claim 4. Instead, this claim was objected to as being dependent upon a rejected base claim. Applicants have amended claim 1 to incorporate the limitations of claim 4 and its intervening claim 3. As a consequence, original claims 3 and 4 have been cancelled. It is believed that amended claim 1 and its dependent claims 2 and 5-6 are now in condition for allowance.

Applicants have proposed new claims 8-9 which depend from now allowable claim 1. These claims define the diameter of the liposomes and find support in Example 2 in the specification. It is believed that these claims are allowable along with their parent claim 1.

Applicants have further proposed new independent claim 10 and dependent claims 11-13. New claim 10 essentially incorporates the limitations of claims 1, 2 and 6, and is believed to be allowable over the art of record. Original claim 2, which defines the isoflavone aglycone as selected from genistein and daidzein, was rejected as anticipated by or obvious in view of several references. Original claim 6, which defines the concentration of the isoflavone aglycone, was rejected as obvious in view of several references. However, with respect to claim 6, it was acknowledged that the cited art does not teach the claimed concentration. The rejection of claim 6 was instead premised on an "obvious to experiment" assertion. It is believed that the Office Action has failed to make out a *prima facie* case for obviousness and that new claim 10, which incorporates the concentration limitation of original claim 6, is allowable.

Claim 6, with the concentration limitations, was rejected as obvious in view of either the Nippon Oils, Hwang or Peters references. None of these references discloses any concentration of isoflavone aglycones, let alone the claimed combination. Nevertheless, this claim was rejected on the grounds that it would have been obvious to "optimize effective amounts of active ingredients" as "motivated by routine practice to optimize the concentration of isoflavones in the composition of any one of the references, with a reasonable expectation for successfully obtaining a composition a composition [sic] of isoflavones and liposomes".

This statement does not provide any motivation whatsoever for "optimizing" the concentration of the isoflavone aglycones. Obviously, optimization of a parameter must be directed toward a particular result or performance characteristic. No meaningful desired result or characteristic has been set forth in this rejection. Certainly, "obtaining a composition of ... isoflavones and liposomes" provides no guidance as to how to "optimize" the concentration of isoflavone aglycones. The cited references themselves are of no help: Peters is concerned with providing a stable aqueous dispersion of nutritional isoflavones; Hwang is directed to a treatment for cystic fibrosis; and Nippon Oils describes a use as an anti-coagulant, vasodilator, and other non-cosmetic applications. Since no *prima facie* case of obviousness has been established with respect to these three references, it is suggested that this rejection is inapplicable to new claim 10, which incorporates the limitations of rejected claim 6.

Claim 6 was further rejected as obvious in view of the combination of Chikamatsu and Matsuda with Lanzendörfer, or over the combination of Saruno and Kikuchi with Lanzendörfer. Again, none of the cited references discloses the claimed concentration, so the "obvious to experiment" standard was applied. The same statement of motivation was advanced, namely to optimize the concentration with a reasonable expectation for successfully obtaining a composition of isoflavones and liposomes. For the reasons stated above, this statement of motivation is insufficient to establish a *prima facie* case for obviousness. It is again suggested that this rejection is inapplicable to claim 10.

Finally, claim 6 was rejected as obvious over the combination of Saruno or Gorbach with Lanzendörfer. As recognized in the Office Action, the cited prior art does not disclose Applicants' claimed concentration of isoflavone aglycone. In fact, the only cited reference with a discernable description of concentration is Gorbach (US 6,060,070), which discloses a concentration of isoflavenoid to base (that is not a liposome) of between 1 and 40 mg per gram. When this cited concentration is translated to the claimed units (mg./kg.) the concentration equates to 1000-40,000 mg. per kg, which is 10 to 2000 times greater than Applicants' claimed concentration. To sustain the "obvious to experiment" rejection of original claim 6 (and by extension new claim 10) there must be some motivation to both alter the base of Gorbach and dramatically lower the concentration of the isoflavone aglycone from the disclosed levels. There is motivation for neither in the cited art.

It was suggested in the Office Action that a person of ordinary skill would naturally turn to the Lanzendörfer reference to substitute the bases of Gorbach or Saruno with the liposome base of Lanzendörfer. The Lanzendörfer reference does disclose liposomes as one of many "penetration promoters"; however, Lanzendörfer does not distinguish among the many choices described at col. 17, lines 44-52. This reference provides no guidance to the person of ordinary skill in the art as to a single choice among the many. Any motivation provided by Lanzendörfer would, at best, be to experiment with the enumerated choices of Lanzendörfer, since the reference makes no distinction among the choices based on desired characteristics and performance.

Lanzendörfer certainly does not provide any suggestion that the concentrations disclosed in Gorbach must be altered, regardless of which of the many "penetration promoters" is selected. Thus, contrary to the assertion in the Office Action, it would not be obvious to experiment with combining the isoflavone aglycone of Gorbach with one of the many "penetration promoters" of Lanzendörfer, while also significantly modifying the concentration from that disclosed in Gorbach.

Moreover, neither Lanzendörfer nor any of the other cited references, provide any suggestion or motivation for altering the concentration of the isoflavone aglycones. As explained above, the recited concentration in Gorbach is at least ten times greater than the maximum claimed concentration in Applicants' claims 6 and 10. There is no suggestion in Gorbach that other concentrations may be acceptable where a different base is used. In fact, Gorbach does not suggest that the concentration of isoflavenoids bears any relationship at all to the nature of the topical base. Adding the Lanzendörfer reference provides no suggestion of motivation for altering the Gorbach concentrations. Accepting that Lanzendörfer teaches the use of a liposome as a topical base, the acknowledged purpose is to improve penetration into the skin – a property provided by the liposome and not by the isoflavones of Gorbach. Thus, neither Lanzendörfer nor Gorbach, whether taken alone or in combination, provides any suggestion or motivation for dramatically altering the isoflavone concentrations of Gorbach to meet the limitations in Applicants' claims 6 and 10.

Moreover, Applicants' invention of a cosmetic formed by incorporating a genistein or daidzein into a liposome at a concentration of between 20 to 100 mg per kg of cosmetic achieves more than simply improved penetration of the composition into the skin. The

inventive concentration also produces therapeutically significant results in the treatment of cellulites, synthesis of skin pigments, and the thickening and strengthening of certain tissues, among other results. None of the references of record disclose treatments, whether or not cosmetic-based, that produce these results. The experimentation needed to combine the cited references and still produce Applicants' claimed invention is much more than simply adjusting concentrations to optimize penetration into the skin.

When this foundation for the obviousness rejection of original claim 6 is dissolved, it becomes clear that the combinations and modifications among the cited references can only be achieved with Applicants' disclosure and claims as a blueprint. In other words, there is nothing in any of the references or the recited "reasonable expectations" that would guide a person of ordinary skill to alter the cited references in the manner suggested in this Office Action. It is therefore believed that new claims 10-13 are novel and non-obvious over the art of record.

Entry of the foregoing amendments in the present application is requested. The limitations of claim 4, which was deemed allowable, have been incorporated into claim 1, so this claim and its dependent claims 2 and 5-9 should be in condition for allowance. Applicants' new claims 10-13 are also believed to be allowable on the grounds set forth above. Reconsideration of this application and timely issuance of a Notice of Allowance is hereby requested. The Examiner is invited to contact the undersigned agent if further issues arise with respect to this application.

Respectfully submitted,



December 30, 2002

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MARKED-UP COPY OF THE AMENDED CLAIMS

Please cancel claims 3 and 4.

Please amend claims 1, 2 and 6 as follows:

1. (amended) A cosmetic comprising:
at least one isoflavone aglycone in a biologically active form as active component,
said at least one isoflavone aglycone being incorporated into liposomes; and
at least one algal extract including an extract of algae of the genus *Spirulina*.
2. (amended) The cosmetic of claim 1, wherein said at least one isoflavone aglycone
is selected [form] from the group consisting of genistein and daidzein.
6. (amended) The [cosmetics] cosmetic of claim 5[.], wherein the concentration of
said isoflavone aglycone is from 20 to 100 mg per kg of the cosmetic.

Please add the following as new claims 8-13:

- 8. The cosmetic of claim 1, wherein said liposomes have a diameter of less than
140 nm. --
- 9. The cosmetic of claim 8, wherein said liposomes have a diameter of between
100nm and 140 nm. --
- 10. A cosmetic comprising at least one isoflavone aglycone in a biologically active
form as active component, said at least one isoflavone aglycone selected from the group
consisting of genistein and daidzein, said at least one isoflavone aglycone being incorporated
into liposomes and in a concentration of from 20 to 100 mg per kg of the cosmetic. --
- 11. The cosmetic of claim 10, further comprising at least one algal extract. --

- 12. The cosmetic of claim 11, wherein said at least one algal extract is an extract of the genus *Spirulina*. --
- 13. The cosmetic of claim 10, wherein said liposomes have a diameter of between 100nm and 140 nm. --

CLEAN COPY OF THE AMENDED CLAIMS

1. A cosmetic comprising:
at least one isoflavone aglycone in a biologically active form as active component,
said at least one isoflavone aglycone being incorporated into liposomes; and
at least one algal extract including an extract of algae of the genus *Spirulina*.
2. The cosmetic of claim 1, wherein said at least one isoflavone aglycone is
selected from the group consisting of genistein and daidzein.
6. The cosmetic of claim 5, wherein the concentration of said isoflavone aglycone
is from 20 to 100 mg per kg of the cosmetic.
8. The cosmetic of claim 1, wherein said liposomes have a diameter of less than
140 nm.
9. The cosmetic of claim 8, wherein said liposomes have a diameter of between
100nm and 140 nm.
10. A cosmetic comprising at least one isoflavone aglycone in a biologically active
form as active component, said at least one isoflavone aglycone selected from the group
consisting of genistein and daidzein, said at least one isoflavone aglycone being incorporated
into liposomes and in a concentration of from 20 to 100 mg per kg of the cosmetic.
11. The cosmetic of claim 10, further comprising at least one algal extract.
12. The cosmetic of claim 11, wherein said at least one algal extract is an extract
of the genus *Spirulina*.

13. The cosmetic of claim 10, wherein said liposomes have a diameter of between 100nm and 140 nm.